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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,229	08/30/2005	Ilaria Capua	4041720003O0	9235

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,229	CAPUA ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 7-17* is/are pending in the application.

4a) Of the above claim(s) *12-14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/17/09 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds of differentiating the populations are now that claim 1 requires all samples to be from vaccinated birds.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Capua *et al.* (Veterinary Record 2000, Vol 147, No 26 page 751 from IDS).

Applicant argues that Capua *et al.* is silent on diagnosing infection in birds that received the vaccine (statement from Dec. para. 5). Applicant argues that hurdle is detecting infected birds in a vaccinated population (from para 6 of Dec.). But on the other hand as argued by applicant concerning paragraph 7 of the Dec., the test for neuraminidase was not sensitive or specific to confer specificity. Applicant mentions paras 10-12 of dec

Applicant's arguments and the Declaration of I Capua (Dec.) have been fully considered and not found persuasive.

Capua et al. state that using H7N3 to vaccinate against H7N1 is a marker vaccine or DIVA approach and that the homologous H7 "ensures protection from clinical signs" and "the reduction of shedding" (of infecting virus) (claims 1-3, 10, and 11). Capua et al. teaches that the presence of a different neuraminidase subtype will enable them to discriminate between vaccinated and infected flocks (claim 4).

Because Capua et al. teach that shedding is reduced, not eliminated, that means that antibodies will be produced to the field strain and the antibody can be detected.

Capua et al. teach that this strategy induces specific antibodies for N3.

Applicant's argument (Dec. para 6-9, 11, and 12) that a test might miss "healthy carriers" and that the tests for neuraminidase antibodies are not specific or sensitive is not persuasive because Capua et al. teach that specific antibodies will be produced against N1 and N3. If applicant is trying to say that the reference is not enabled, they would need to present evidence to that fact, that N1 and N3 antibodies cannot be differentiated. While the Dec. states that the prior art assays are not specific or sensitive and full consideration is accorded to that statement, the Capua et al. reference states that it can be done. If applicant is stating that it is unpredictable in this situation to assay for neuraminidase antibodies, applicant needs to state specifically why the Capua et al. reference is lacking. Dec. para 10 agrees with the Capua Dec. that homologous "H7" allows for field virus replication but reduced shedding and clinical signs.

Thus, the claims are anticipated by Capua *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-11, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capua *et al.* (Veterinary Record 2000, Vol 147, No 26 page 751) and Van de Perre et al. (J Clinical Micro. 1988 Vol 26, pages 552-556).

Applicant arguments for Capua *et al.* are discussed above. Applicant mentions paras 10-12 of dec and concludes Van de Perre et al. does not cure the deficiencies of Capua *et al.*

Applicant's arguments and the Declaration of I Capua (Dec.) have been fully considered and not found persuasive.

Applicant's arguments are addressed above.

Capua *et al.* (middle paragraph, page 751) which teach use of homologous H7 and heterologous N3 (in the vaccine strain, H7N3) to differentiate from influenza H7N1 (field strain) by means of an *ad hoc* diagnostic assay that detects specific antibodies to N1 versus N3.

Capua *et al.* is discussed in previous actions and above.

Capua *et al.* does not explicitly teach contacting biological fluid and antigen.

Capua et al does teach that the assay is to detect neuraminidase antibodies.

One of ordinary skill in the art at the time of invention would have known that antibodies come from biological fluid and many methods to assay for antibodies including immunoperoxidase used in ELISA and dip sticks, see Van de Perre et al. abstract and Table 1).

Thus, it would have been prima facie obvious at the time of invention to vaccinate birds with the vaccine of Capua *et al.* to differentiate vaccinated from infected birds using art known methods to detect an antibody with the expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648